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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2011222PC/ko	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/FI2003/000236	International filing date (day/month/year) 27.03.2003	Priority date (day/month/year) 27.03.2002
International Patent Classification (IPC) or national classification and IPC C12P 7/64		
Applicant VALIO LTD et al		

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:

- ☒ (sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 6 of Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and Supplemental Box.

- ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand 11.09.2003	Date of completion of this report 22.06.2004
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FI2003/000236

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1 - 15 as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- pages _____ as originally filed/furnished
- pages* _____ as amended (together with any statement) under Article 19
- pages* 16 - 17 received by this Authority on 01.04.2004
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FI2003/000236

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-20</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-20</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-20</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The most relevant documents cited in the International Search Report are:

- D1: Prima S. Sehanputri et al, Biotechnology for the production of nutraceuticals enriched in conjugated linoleic acid: I. Uniresponse kinetics of the hydrolysis of ~~corn oil~~ by a pseudomonas sp. lipase immobilized in a hollow fiber reactor, Biotechnology and bioengineering, Volume 64, No 5, Sept 1999
- D2: Prima S. Sehanputri et al, Biotechnology for the production of nutraceuticals enriched in conjugated linoleic acid: II. Multiresponse kinetics of the hydrolysis of corn oil by a pseudomonas Sp. Lipase immobilized in a hollow fiber reactor, Biotechnology and bioengineering, Volume 69, No 4, August 2000
- D3: WO9932604A1
- D4: US5856149A
- D5: WO9929886A1

The invention according to claim 1 relates to a process for preparing conjugated linoleic acid (CLA) from oat by microorganism hydrolysis. By using oat, the problems associated with the inhibitory activity of free linoleic acid can be avoided. Further, the problems stemming from the poor solubility of free linoleic acid in water can be avoided.

Document D1 and D2 relates to the hydrolysis of corn oil in the presence of a lipase from Pseudomonas sp. immobilized within the walls of a hollow fiber reactor.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Document D3 relates to linoleate isomerase, a polynucleotide encoding the enzyme or immobilized bacteria containing the isomerase. They are used in a method for producing conjugated linoleic acid from oils such as sunflower oil, safflower oil, corn oil or linseed oil. The immobilized bacterial cell can be a Propionibacterium. The document mentions that the substrate and/or end product may have an inhibitory effect (in example 10 a maximum amount of 200 ppm linoleic acid is used, example 13 suggests the starting material addition in several batches).

Document D4 relates to the use of Lactobacillus for the production of CLA. As starting material, corn oil, sunflower oil, linseed oil and primrose oil are mentioned (column 7, lines 3-5).

Document D5 describes the production of CLA by means of fermentation with proprionic bacteria and bifidobacteria. Plant oil, such as corn oil is used as starting material. The inhibitory effect of free linoleic acid on bacteria is described on pages 11-13.

None of the cited documents discloses or suggests a process with oat as starting material. Documents D3 and D5 mentions the problem with the inhibition effect of free linoleic acid on the bacteria. However, these documents do not disclose the same solution to the problem described. Nothing stated in D1-D5 leads a person skilled in the art to the conclusion that oat can be used as starting material in order to solve the problem. Consequently, the invention according to the claims is novel and involves an inventive step. However, the claims do not meet the requirements of Article 6, see Box VIII.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The subject matter of claims 1-5 and 9-20 is not sufficiently defined. It does not contain the type of microorganism used. This feature is necessary to solve the technical problem with which the application is concerned (Article 6). It has not been shown in the application that all the microorganisms in claims 1-5 and 9-20 have the desired properties. From the wordings of the present claims, the skilled person would therefore not know what type of microorganism he would have to select to obtain the desired effect.

CLAIMS AMENDED ON 1 APRIL, 2004

1. A process for preparing conjugated linoleic acid by microorganisms, **characterized** by hydrolyzing oat fat and isomerizing the linoleic acid released in the hydrolysis into conjugated linoleic acid by the microorganisms.

2. A process according to claim 1, **characterized** in that the grain is untreated oat, pretreated oat or an oat fraction.

3. A process according to claim 1 or 2, **characterized** in that the fat hydrolysis is caused by the enzyme activity of oat.

4. A process according to claim 1 or 2, **characterized** in that the fat hydrolysis is carried out by adding external enzyme activity.

5. A process according to any one of claims 1 to 4, **characterized** in that isomerization is carried out by a beneficial bacterium (bacteria).

6. A process according to claim 5, **characterized** in that the beneficial bacterium is a propionic acid bacterium.

7. A process according to claim 6, **characterized** in that the propionic acid bacterium is a strain belonging to the species *Propionibacterium freudenreichii*, preferably a strain belonging to its subspecies *Propionibacterium freudenreichii* ssp. *freudenreichii* or *Propionibacterium freudenreichii* ssp. *shermanii*.

8. A process according to claim 7, **characterized** in that the propionic acid bacterium is *Propionibacterium freudenreichii* ssp. *shermanii* JS, DSM 7067.

9. A process according to any one of claims 1 to 8, **characterized** in that isomerization is carried out at a pH of about 6.5 to 9.5.

10. A process according to claim 9, **characterized** in that isomerization is preferably carried out at a pH of about 7.0 to 9.0, more preferably at a pH of about 8.0 to 8.5.

11. A process according to any one of claims 1 to 10, **characterized** in that the hydrolysis and isomerization steps are carried out consecutively.

12. A process according to any one of claims 1 to 10, **characterized** in that the hydrolysis and isomerization steps are carried out in parallel.

13. A process according to any one of claims 1 to 12, **characterized** in that the preparation of conjugated linoleic acid occurs in connection with the preparation of a food product.

5 14. A process according to any one of claims 1 to 13, **characterized** in that mainly cis-9, trans-11 isomer of conjugated linoleic acid is formed therein.

10 15. A process according to any one of claims 1 to 14, **characterized** in that conjugated linoleic acid is fixed to solids by adjusting the pH of the reaction mixture to about 3 to 9, preferably to a value lower than 7.0, most preferably to about 4 to 6.

16. A process according to any one of claims 1 to 15, **characterized** in that conjugated linoleic acid is isolated from the reaction broth and possibly dried.

15 17. A process according to any one of claims 1 to 15, **characterized** in that conjugated linoleic acid, bacterial cells and the oat material used as starting material, which is preferably oat material are concentrated and possibly dried.

20 18. A process according to claim 17, **characterized** in that linoleic acid, bacterial cells and oat material used as the starting material are recovered, concentrated and lyophilized.

19. Oat for use in the preparation of conjugated linoleic acid.

20. A process for preparing conjugated linoleic acid from linoleic acid, **characterized** in that oat is used as the source of linoleic acid.